Quality Assurance Manual (QAM)

U.S Army Medical Research Acquisition Activity

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0.0 Table of Contents

0.1 AMENDMENT RECORD

This quality assurance manual (QAM) contains only the pages issued by this facility. The Management Representative (MR) will process all authorized changes, inserting amendment pages into the official distribution copies. The MR will see that obsolete pages are withdrawn from use and disposed of to prevent unintentional usage. This QAM is a controlled copy document. The MR maintains the master copy of this QAM. This master copy is used as the final authority, regarding the latest revision level and amendment status for the USAMRAA QAM.

Issue	Section	Date	Page	Description of revisions	Approval
# 1	1-20	2/10/00	All	Release Draft Quality Assurance Manual	
# 2	1-20	3/14/00	All	Update of Draft Quality Assurance Manual	
# 3	1-20	5/22/00	All	Quality Assurance Manual (QAM)	
# 4	1-20	6/06/00	All	Quality Assurance Manual (QAM)	
#5	1-20	6/9/00	All	Quality Assurance Manual (QAM)	
#6	1-20	12/04/00	All	Quality Assurance Manual (QAM)	
#7	1-20	07/09/01	All	Quality Assurance Manual (QAM)	
#8	1-20	08/03/01	All	Quality Assurance Manual (QAM)	

Prepared By: Michael Stitely	Issue Number: 8
Approved By: Kenneth Connolly	Issue Date: 08/03/01

0.2 CONTROLLED CIRCULATION LIST

Number	Copy Custodian	Signature
1	Deputy for Acquisition Policy and Support/Management Representative	Michael D. Stitely
2	Director	Kenneth B. Connolly

0.3 GLOSSARY

MR - Management Representative

AM – Account Manager

CIO – Chief Information Officer

QAM - Quality Assurance Manual

QPM - Quality Procedures Manual

MC - Master Copy

Standard(s) - industry, national and international quality standards and IS0 9002: 1994

USAMRAA – United States Army Medical Research Acquisition Activity

PO - Purchase Order

I&T - Inspection and Testing

IM&TE - Inspection, Measuring, and Test Equipment

H,S,P,P&D - Handling, Storage, Packaging, Preservation and Delivery

IQA - Internal Quality Audits

C&PA - Corrective and Preventive Action

FAR – Federal Acquisition Regulations

DFARS – Defense Federal Acquisition Regulation Supplement

AFARS – Army Federal Acquisition Regulation Supplement

DODGAR – Defense Grants and Assistance Regulation

USAMRMC-AI – USAMRMC Acquisition Instruction

ERMS- Extramural Research Management System

1.0 MANAGEMENT RESPONSIBILITY

1.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 1-Element 4.1 Management Responsibility.

1.2 Responsibility and Authority

The Director, the Deputy for Business Management, the Deputy for Business Operations, and the Deputy for Business Support have the responsibility and authority for overall administration of USAMRAA quality activities.

1.3 Quality System Requirements

1.3.1 Quality Policy – an Activity quality policy has been established identifying quality system goals and objectives. This policy has been communicated to all employees and is maintained as the highest priority within the activity. Each employee understands his or her role.

1.3.2 Responsibility and Authority - the Responsibility and Authority for all activities that affect quality have been defined in both quality system documentation and job descriptions.

1.3.3 Resources - adequate resources required to complete quality system activities have been defined in both the quality system documentation and job descriptions.

1.3.4 Management Representative - the Deputy for Business Management has been appointed as the MR by the Director. The MR has been granted full authority for the establishment, implementation, maintenance, verification and reporting of quality assurance system activities.

1.3.5 Management Review - the MR schedules Management Review meetings with executive management. These reviews determine the effectiveness and suitability of the implemented quality system requirements. Minutes of these review meetings are maintained.

1.4 Related and Support Documentation

2QP01-01 Management Responsibility Procedure
2QP01-02 Management Review Meetings Procedure
Quality Policy Statement

2.0 QUALITY SYSTEM

2.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 2 - Element 4.2 Quality System.

2.2 Responsibility and Authority

The Director, the Deputy for Business Management, the Deputy for Business Operations, and the Deputy for Business Support have the responsibility and authority for implementing the requirements of the USAMRAA quality system activities.

2.3 Quality System Requirements

2.3.1 Quality Assurance Manual and Procedures have been created to address all requirements of the standard. USAMRAA is using a four-tiered documentation structure as follows:

- Level I - Quality Policy Statement and Quality Assurance Manual,
- Level II - Quality Procedures Manual
- Level III - Work Instructions/Regulations and Job Descriptions, and
- Level IV - Quality System Forms and Records.

2.3.2 Quality Planning - quality planning activities are carried out to ensure that all specified requirements have been addressed and met. Quality System Documentation controls the processes and methods used to meet these requirements. Quality planning methods and practices identify and may include the following:

- Preparation of quality plans,
- Identification and acquisition of controls, processes, equipment, fixtures, resources and skills,
- Ensuring the compatibility of all aspects of quality,
- Updating of quality control and inspection techniques,
- Standards of acceptability, and
- Identification and preparation of quality records.

2.4 Related and Support Documentation

2QP02-01 Quality Planning Procedure

3.0 CUSTOMER AGREEMENT REVIEW

3.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 3 -Element 4.3 Contract Review.

3.2 Responsibility and Authority

The Deputy for Business Operations, Deputy for Business Operations, and the Account Managers have the responsibility and authority for implementing the requirements of Contract and Assistance Reviews.

3.3 Customer Agreement Review

3.3.1 Procedures exist to control the methods and practices used by USAMRAA to complete customer contract and assistance reviews and related amendments.

3.3.2 All agreements adequately define the specified requirements. Differences between specified requirements and capabilities will be resolved prior to acceptance. This also includes verbal orders.

3.3.3. Amendments to agreements are defined and communicated to all affected functional groups.

3.3.4 USAMRAA ensures that they have the capability to meet the agreement requirements prior to acceptance. Records of contracts and amendments are maintained (4.16).

3.4 Related and Support Documentation

2QP03-01 Customer Agreement Review and Amendment Procedure
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI, SPS Manual)

4.0 DESIGN CONTROL

The USAMRAA does not design anything at this time. Should USAMRAA undertake design in the future the design process will conform to the specified requirements of ISO 9001: 1994.

5.0 DOCUMENT AND DATA CONTROL

5.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 5 -Element 4.5 Document and Data Control.

5.2 Responsibility and Authority

The Deputy for Business Management, Deputy for Business Operations, the Chief of the Business Oversight Branch, Chief of the Policy and Quality Assurance Branch, and Deputy for Business Support have the responsibility and authority for implementing the requirements of Document and Data Control.

5.3 Document and Data Control

5.3.1 Documented procedures controlling all aspects of the creation review, approval, modification, issue, release, and other activities associated with document and data control are adhered to. These controls apply to all documents regardless of their origin.

5.3.2 Current revision levels of all documents are maintained in the areas where the work described in the documents is being carried out. A master list or equivalent document control procedure identifying the current revision status of documents is maintained. This listing includes current revision-level information, and is available to all employees that need this information to carry out their activities. Obsolete documents are marked to ensure that they are not used to make decisions that may affect quality. Obsolete documents are promptly removed from all points of issue or use. The document control officer within the organization identifies and revises these documents. Historical data is marked accordingly and maintained for reference purposes.

5.3.3 All changes to documents and data are reviewed by the same functions/organizations that performed the original review and approval. These same functions/organizations have access to any background information to aid them in their review and approval. The nature of the change is clearly identified, where applicable.

5.4 Related and Support Documentation

2QP05-01 Document and Data Control Procedure

6.0 PURCHASING

6.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 6 - Element 4.6 Purchasing.

6.2 Responsibility and Authority

The Account Managers, Branch Chiefs, and the Contract Specialists have the responsibility and authority for implementing the requirements of Purchasing.

6.3 Purchasing

Documented procedures controlling all aspects of purchasing are in use. These controls apply to raw materials, components, assemblies, subassemblies, final assemblies, services, etc. These procedures control the following activities:

- Identification, selection and evaluation of potential and current subcontractors,
- Determination of subcontractors capabilities and abilities to meet specified requirements,
- Determination of the type and extent of controls that are applied to each subcontractor,
- Development of subcontractor capabilities to meet standard(s) requirements,
- All award information contains adequate detail to ensure that all specified requirements have been adequately defined,
- Purchasing personnel, in advance of the award being placed with the subcontractor, carries out reviews of all related information,
- On-site verification is not routinely used to determine acceptability of our subcontractors or the subsequent performance of the materials these subcontractors provided,
- If USAMRAA proposes to verify purchased product at the subcontractor premises, arrangements are specified in the purchasing documents. Such verification is not a part of the USAMRAA quality system at this time, and
- If specified in the contract, USAMRAA customers are afforded the right to verify, at the subcontractor premises, that product conforms to specified requirements. Such verification is not used in place of verification measures used by USAMRAA. Verification by the customer does not absolve the subcontractor of the obligation to provide quality products, nor preclude

subsequent rejection by the subcontractor.

6.4 Related and Support Documentation

2QP06-01 Purchasing Procedure
FAR/DFARS/AFARS/AI/DODGAR/SPS

7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

7.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 7 - Element 4.7 Customer-Supplied Product.

7.2 Responsibility and Authority

The Deputy for Business Operations has the responsibility and authority to implement the requirements of Control of Customer Supplied Product.

7.3 Control of Customer-Supplied Product

Currently there is no Customer-Supplied Product-if in the future we handle such products (as defined at paragraph 3.1 of ISO 9002:1994) a procedure for handling same will be created.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

8.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 8 -Element 4.8 Product Identification and Traceability.

8.2 Responsibility and Authority

The Deputy for Business Operations, Deputy for Business Support, Account Managers, Contracting Specialists and the Procurement Technicians have the responsibility and authority for implementing the requirements of Product Identification and Traceability. The Chief Information Officer has the responsibility and authority for the electronic systems oversight.

8.3 Product Identification and Traceability

Documented procedures exist to control all aspects of product identification and traceability. These controls apply to all situations where specified requirements indicate a need for identification and/or traceability. These controls include the following:

- Components of the contracts are identified through the use of specific labeling and other methods; and
- Revisions to the contracts are a permanent part of the product. This identification is maintained from the time the purchase requisition is received until close out of the project.

8.4 Related and Support Documentation

2QP08-01 Product Identification and Traceability Procedure

9.0 PROCESS CONTROL

9.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 9 - Element 4.9 Process Control.

9.2 Responsibility and Authority

The Deputy for Business Management/MR, Deputy for Business Operations, the Deputy for Business Support, Branch Chiefs, the Account Managers and the Contract Specialists have the responsibility and authority for implementing the requirements of Process Control.

9.3 Process Control

Documented controls, plans and procedures exist to govern the methods and practices used to complete activities and processes. These controls include the following:

- The use of suitable review and office equipment, including a suitable working environment;
- Compliance with reference standards/codes, quality plans and/or documented procedures;
- Monitoring and control of suitable process parameters and agreement characteristics;
- The approval of processes;
- The criteria for workmanship (written standards, representative samples or illustrations); and
- Suitable maintenance of office equipment.

9.4 Related and Support Documentation

2QP09-01 Process Control Procedure

10.0 INSPECTION AND TESTING

10.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 10 - Element 4.10 Inspection and Testing.

10.2 Responsibility and Authority

The Deputy for Business Management, the Deputy for Business Operations, the Deputy for Business Support, Branch Chiefs, and the Account Managers have the responsibility and authority for implementing the requirements of Inspection and Testing.

10.3 Inspection and Testing (I&T)

Documented procedures have been established and maintained for inspection and testing to verify that specified requirements are met. The inspection, testing and records are detailed in the documented procedures.

Receiving inspection and testing – USAMRAA ensures that incoming product is not used or processed until it has been inspected or verified as conforming to specified requirements. In determining the amount of receiving inspection, consideration shall be given to the amount of control that will be exercised at the subcontractor's premises and the evidence of conformance provided. No provisions are in place in the event that urgent release is permitted by 4.10.2.3 of the standard because this is not applicable to our process.

In-process inspection and testing – The product is inspected and tested as required by the documented procedures, and the product is held until the required inspections and testing have been completed, or necessary reports have been received and verified.

Final inspection and testing – Final inspection shall be carried out in accordance with the documented procedures and shall require that all specified inspections and testing, including those specified on receipt or in-process, have been carried out.

Inspection and test records – The quality records (4.16) shall clearly show that the product

passed/failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedure for Control of nonconforming product (4.13) shall apply.

10.4 Related and Support Documentation

2QP10-01 Inspection and Testing Procedure
2QP13-01 Control of nonconforming product

11.0 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

11.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 11 -Element 4.11 Control of Inspection, Measuring and Test Equipment.

11.2 Responsibility and Authority

The Deputy for Business Management has the responsibility and authority for implementing the requirements of the Control of Inspection, Measuring, and Testing Equipment.

11.3 Inspection, Measuring and Test Equipment

Due to USAMRAA's servicing nature, they do not currently utilize any IM&TE.

If in the future USAMRAA should have the need for "traditional" IM&TE equipment, they shall adhere to the requirements set forth in Element 11 of the ISO 9002:1994 Standard.

12.0 INSPECTION AND TEST STATUS

12.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 12 - Element 4.12 Inspection and Test Status (I&T).

12.2 Responsibility and Authority

The Deputy for Business Management, the Deputy for Business Support, the Deputy for Business Support, and the Account Managers have the responsibility and authority for implementing the requirements of Inspection and Test Status.

12.3 Inspection and Test Status

Documented procedures provide for the identification of inspection and test status throughout the process which ensures that only product that has passed the required inspections and tests are dispatched. These procedures control the methods for identifying conforming and nonconforming products based on their inspection and test results.

12.4 Related and Support Documentation

2QP12-01 Inspection and Testing Status Procedure

13.0 CONTROL OF NONCONFORMING PRODUCT

13.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 13 - Element 4.13 Control of Nonconforming Product.

13.2 Responsibility and Authority

The Deputy for Business Management, the Deputy for Business Operations, the Deputy for Business Support, and the Account Managers have the responsibility and authority to implement the requirements of the Control of Nonconforming Product.

13.3 Control of Nonconforming Product

Documented procedures controlling all aspects of nonconforming products are in use. These controls include the following activities:

- Methods and practices used to identify, document, evaluate, and segregate nonconforming product;
- Methods used to document characteristics and conditions;
- Methods used to notify functional organizations affected;
- Methods used to evaluate and carry out disposition include rework, or reject; and
- Rework and /or repaired product shall be re-inspected in accordance with documented instructions.

13.4 Related and Support Documentation

2QP13-01 Control of Nonconforming Product Procedure

14.0 CORRECTIVE AND PREVENTIVE ACTION

14.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 14 - Element 4.14 Corrective and Preventive Action (C&PA).

14.2 Responsibility and Authority

The Director, the Deputy for Business Operations and the Deputy for Business Management and the Deputy for Business Support have the responsibility and authority to implement the requirements of Corrective and Preventive Action.

14.3 Corrective Action

Documented procedures controlling all aspects of Corrective Action are in use. These procedures control the following:

- Handling of customer complaints and product nonconformity;
- Investigation and recording of product, process, and quality system requirements;
- Determination of root cause(s) of nonconforming situations;
- Identification and implementation of Corrective Action with intent of preventing
- Recurrence of nonconforming situation;
- Initiation and effective implementation of Corrective Action; and
- Maintenance of records associated with Corrective Action.

14.4 Preventive Action

Documented procedures controlling all aspects of Preventive Action are in use. These procedures control the following:

- The uses of the appropriate sources of information to detect analyze and eliminate potential causes of nonconformity;
- Determination of steps to prevent nonconforming situations;
- Initiation and effective implementation of Preventive Action;

- Reporting of Preventive Action results at Management Review Meetings, and
- Maintenance of records associated with Preventive Action.

14.5 Related and Support Documentation

2QP01-02 Management Review Meeting Procedure
2QP14-01 Corrective and Preventive Action Procedure
2QP17-01 Internal Quality Audit Procedure

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

15.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 15 - Element 4.15 Handling, Storage, Packaging, Preservation and Delivery (H,S,P,P&D).

15.2 Responsibility and Authority

The Account Managers, Branch Chiefs, and the Contract Specialists have the responsibility and authority to implement the requirements of Handling, Storage, Packaging, Preservation and Delivery. The Chief Information Officer has the responsibility and authority of maintaining all electronic systems to implement the requirements Handling, Storage, Packaging, Preservation and Delivery.

15.3 Handling, Storage, Packaging, Preservation and Delivery (H, S, P, P&D)

Documented procedures exist to control all aspects of H, S, P, P&D. These procedures are in use and control the following activities:

15.3.1 Handling: Handling methods and practices are intended to prevent damage and deterioration of material and products throughout the process.

15.3.2 Storage: Clearly defined methods and practices are in use for the receipt and dispatching of items. Files are periodically assessed to detect damage or deterioration.

15.3.3 Packaging: Methods of packing, packaging and marking of packaging materials are controlled to ensure that all specified requirements have been met.

15.3.4 Preservation: Measures are taken to preserve materials and products to prevent damage and deterioration.

15.3.5 Delivery: Practices and procedures are in use that provides for the protection of products after final inspection and testing. As required, this protection shall apply to the delivery of the product to the customer.

15.4 Related and Support Documentation

2QP15-01 Handling, Storage, Packaging, Preservation, and Delivery Procedure

16.0 CONTROL OF QUALITY RECORDS

16.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 1 - Element 4.16 Control of Quality Records.

16.2 Responsibility and Authority

The Deputy for Business Management/MR and the Deputy for Business Operations have the responsibility and authority to implement the requirements of Control of Quality Records

16.3 Control of Quality Records

Documented procedures controlling all aspects of quality records are in use. These procedures control the following:

- Controls apply to all company and subcontractor related quality records;
- Identification, collection, indexing, access, filing, storage, maintenance, and disposition;
- Records are legible and maintained in a retrievable manner;
- Records are maintained in a storage environment that prevents damage and deterioration;
- Electronic records are backed-up and maintained to prevent loss or damage;
- Record retention periods are specified and conform to customer requirements; and
- Records are made available to customers upon request.

16.4 Related and Support Documentation

2QP16-01 Control of Quality Records Procedure

17.0 INTERNAL QUALITY AUDITS

17.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 17 - Element 4.17 Internal Quality Audits.

17.2 Responsibility and Authority

The Deputy for Business Management/MR, the Lead Auditor, and the Internal Quality Audit Team have the responsibility and authority to implement the requirements of Internal Quality Audits.

17.3 Internal Quality Audits (IQA)

- IQA are carried out to verify that planned and documented procedures and other quality system documentation is in conformity;
- IQA are scheduled based on the impact on quality and quality performance;
- IQA are carried out against all elements of the standard that apply to the operation being audited;
- IQA are completed by trained and qualified personnel who understand the standard, auditing requirements, and basic communication skills;
- Personnel that are independent of the functional area being assessed and free of bias or influence carry out IQA;
- IQA results are documented and are communicated to the auditee;
- Auditee management determines and implements timely corrective action;
- Follow-up activities are carried out to verify the effectiveness of IQA corrective action; and
- Records of IQA are maintained (4.16).

17.4 Related and Support Documentation

2QP17-01 Internal Quality Audits Procedure

18.0 TRAINING

18.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 18 - Element 4.18 Training.

18.2 Responsibility and Authority

The Director, the Deputy for Business Management, the Deputy for Business Support, and the Branch Chiefs have the responsibility and authority to implement the USAMRAA Training requirements.

18.3 Training

Documented procedures controlling all aspects of training are in use. These procedures control the following:

- Training needs are identified based on individual job assignments and business needs;
- Training necessary to perform assigned jobs is provided;
- Individuals are qualified based upon their abilities, on-the-job training, education and other special skills;
- Grandfathering is permitted based upon on-the-job training and experience. This information is documented;
- Evaluation of the effectiveness of all training is carried out in the form of supervisor review on an annual basis; and
- Records of training and qualifications are maintained (4.16).

18.4 Related and Support Documentation

2QP18-01 Training Procedure

19.0 SERVICING

19.1 Scope and Purpose

THIS ELEMENT DOES NOT APPLY TO THE CURRENT ACTIVITIES TAKING PLACE AT USAMRAA. IF IN THE FUTURE SERVICING BECOMES A PART OF USAMRAA'S QUALITY SYSTEM, THE NECESSARY QUALITY SYSTEM DOCUMENTATION WILL BE IMPLEMENTED TO CONTROL THESE ACTIVITIES.

20.0 STATISTICAL TECHNIQUES

20.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): Section 20 - Element 4.20 Statistical Techniques.

20.2 Responsibility and Authority

The Deputy for Business Management and the Deputy for Business Support have the responsibility and authority to implement the requirements of Statistical Techniques.

20.3 Statistical Techniques

Documented procedures controlling all aspects of Statistical Techniques are in use. These procedures control the following activities and requirements:

- Determination of the need for statistical techniques;
- Selection of appropriate statistical techniques for purpose; and
- Provide basic training to individuals carrying out statistical techniques- related activities, to ensure proper use and knowledge.

20.4 Related and Support Documentation

2QP20-01 Statistical Techniques Procedure